SECTION 2

NOV 1 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: Pure Water Solutions, Inc.
3925 West Northside Drive
Jackson, MS 39209
Contact Person: John Bower, President

Date of Summary: April 2, 2001

Device Name: Pure Water Solutions Central Water System for Hemodialysis

Device Classification Name: Water purification system for hemodialysis (78 FIP), 21 CFR 878.5665

Legally Marketed Devices to which Equivalence is Claimed: The legally marketed predicate devices are the Mar Cor Complete Treatment System for Kidney Dialysis (K945559) determined to be substantially equivalent to a legally marketed (preAmendment) device on May 23, 1996, U.S. Filter/Ionpure, Inc. Water Purification System for Hemodialysis (K980182) determined to be substantially equivalent to a legally marketed (preAmendment) device on November 16, 1998, and Zyzatech Water System, Inc. Water Purification Systems and Components and Portable Reverse Osmosis System (K964539) determined to be substantially equivalent to a legally marketed (preAmendment) device on September 9, 1997.

Device Description: The Pure Water Solutions Central Water System for Hemodialysis is a complete system designed for the purification of water for use in hemodialysis. The major components of the system are not manufactured by Pure Water Solutions, Inc., but are specified, purchased and installed based on the user's individual facility and system requirements. The Pure Water Solutions Central Water System for Hemodialysis consists of pretreatment components, a reverse osmosis (RO) unit, and product water distribution components.

The Pure Water Solutions Central Water System for Hemodialysis produces product water that meets the requirements of ANSI/AAMI RD5-1992, Hemodialysis Systems.

Intended Use: The Pure Water Solutions Central Water System for Hemodialysis is intended for use with a hemodialysis system and is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate, and to produce purified

water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection.

Descriptive Summary of Technological Characteristics and Those of Predicate Devices: The Pure Water Solutions Central Water System for Hemodialysis utilizes the same types of components in the same configuration as the predicate devices. The indications for use of these devices systems are substantially equivalent.

Conclusion: The information and data provided in this 510(k) Notification establish that the Pure Water Solutions Central Water System for Hemodialysis is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

Mr. John Bower
President
Pure Water Solutions, Inc.
3925 West Northside Drive
JACKSON MS 39209

Re: K011005
Trade/Device Name: Direct & Indirect Feed Central Water Systems for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: July 29, 2002
Received: August 7, 2002

Dear Mr. Bower:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

April 2, 2001

510(k) Number: K011005

Device Name: Pure Water Solutions Central Water System for Hemodialysis

Indications for Use: The Pure Water Solutions Central Water System for Hemodialysis is intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate, and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011005